SM.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,957	11/13/2001	Hans Herweijer	Mirus.025.01	8989

7590 04/08/2004

Mark K. Johnson
PO Box 510644
New Berlin, WI 53151-0644

EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary	Application No.	Applicant(s)	
	09/992,957	HERWEIJER ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *13-24 and 28-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *18 January 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This is the First Office Action on the Merits of the application filed 13 November 2001, which claims benefit of US Provisional application 60/248,275 filed 14 November 2000. Claims 1-33 are pending.

Election/Restrictions

Applicant's election of Group I (claims 1-12 and 25-27) in the Paper filed 20 February 2004 is acknowledged. Because applicant did not distinctly and specifically point out errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-24 and 28-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Claims 1-12 and 25-27 are presently under consideration.

Specification

The disclosure is objected to because of the following informalities: The drawings include four figures but only two figures are described in the "Brief Description of the Drawings". The specification should include a brief description of each drawing.

Appropriate correction is required.

Claim Objections

Claims 25 and 26 are objected to because of the following informalities: The phrase "comprising of administering" in the first line of the claims is grammatically incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 25 and 26 are indefinite in failing to set forth a terminal process step that clearly relates back to the preamble. It is therefore unclear whether the use set forth in the preamble requires additional process steps that are not set forth in the body of the claim. Claim 1 is directed to a method for inducing an antigen-specific immune response; however, the terminal process step recites only that a nucleic acid is delivered to a vertebrate cell. Furthermore, claim 1 is written as though the method comprises a product. A method comprises process steps, which might be directed to making or using a product. Although a product might be the object of a method claim it is not the subject. Therefore, claim 1 should be rewritten as a series of process steps directed to using the nucleic acid of the claim.

Claims 25 and 26 are directed to a method for generating an antibody response or cellular immune response, respectively; however, the terminal process step recites that the nucleic acid is administered in an amount sufficient to induce "the desired immune response". The phrase "the

desired immune response" does not have clear antecedent basis in the claim and therefore the relationship of the terminal step to the preamble is unclear.

Claims 2-12 are indefinite insofar as they depend from claim 1.

Claim 12 is additionally indefinite in reciting, "the host is a mammal". Claim 1, from which claim 12 depends, recites, "the nucleic acid is delivered to a vertebrate host cell". Claim 1, as written, does not require that the nucleic acid be delivered to the host cell in the vertebrate (*i.e.*, *in vivo*); therefore, the vertebrate is not necessarily the host. By merely stating "the host is a mammal" it is unclear whether claim 12 is now limited to delivering the nucleic acid to the cell *in vivo* such that the mammal is the host, or whether applicant intends that the "host cell" be limited to a mammalian host cell. If the latter is the case, it is recommended that the claim be amended to read, "the vertebrate is a mammal".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 10, 12 and 26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 66 of copending

Application No. 10/202,858. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 66 of the '858 application is fully encompassed by the instant claims and therefore anticipates the claims.

Claims 66 of the '858 application is directed to a process for inducing a detectable cellular immune response in a mammal comprising administering *in vivo* into tissue of the mammal a composition comprising a noninfectious, nonintegrating DNA comprising a promoter operably linked to a sequence encoding an immunogen, said DNA being complexed into a cationic lipid, wherein said composition is administered in an amount sufficient that uptake of said DNA into cells of the mammal occurs, and sufficient expression of said immunogen results, to induce the detectable cellular immune response. Each of the limitations of the claim are recited in, or generally encompassed by the limitations of the instant claims 1, 10, 12, 26 and 27; therefore, the claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-12 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones *et al. Vaccine*. 1997 Jun; 15(8):814-7 (made of record in the IDS filed 18 January 2003).

Jones *et al.* teaches a genetic immunization method for inducing an antigen-specific immune response, comprising administering to a mammalian host cell a nucleic acid sequence encoding an antigenic peptide operatively linked to one or more control sequences such that the nucleic acid sequence is expressed in a host cell (see especially the first full paragraph in the right column on page 814, the paragraph bridging pages 815-816, the paragraph bridging the left and right columns on page 816 and Figure 1 and the caption thereto). Thus, Jones *et al.* teaches a method comprising all of the limitations of independent claim 1, and dependent claim 12.

Given that lymphoid cells are found throughout the body and at the site of administration in the method of Jones *et al.*, absent evidence to the contrary, the skilled artisan would understand that the method of Jones *et al.* includes administration to a lymphoid cell according to claim 2. Furthermore, given the oral route of administration, the skilled artisan would also understand that the host cell of Jones *et al.* includes a gut-associated lymphoid cell according to claim 3 in the intestinal lumen according to claim 27.

Jones *et al.* contemplates the method wherein the delivery step is through oral administration according to claim 6 (*Id.*) and claim 9; wherein the nucleic acid is further protected by a coating according to claim 7 which is an enteric coating according to claim 8 (*i.e.*, poly(DL-lactide-co-glycolide)); wherein the sequence is a DNA sequence according to claim 10 which is a plasmid according to claim 11.

Jones *et al.* also teaches that the method can be used to generate an antibody response in a vertebrate host according to claim 25 or to generate a cellular immune response in a vertebrate host according to claim 26 (see especially Figure 1 and the caption thereto).

The method of Jones *et al.* comprises all of the limitations of the instant claims; therefore, the claims are anticipated by Jones *et al.*

Claims 1-3, 6-12, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen *et al. J Virol.* 1998 Jul;72(7):5757-61 (made of record in the IDS filed 18 January 2003).

Chen *et al.* teaches a genetic immunization method for inducing an antigen-specific immune response, comprising administering to a mammalian host cell a nucleic acid sequence encoding an antigenic peptide operatively linked to one or more control sequences such that the nucleic acid sequence is expressed in a host cell (see especially paragraphs 2-4 in the left column on page 5758 and Figure 2 and the caption thereto). Thus, Chen *et al.* teaches a method comprising all of the limitations of independent claim 1, and dependent claim 12.

Given that lymphoid cells are found throughout the body and at the site of administration in the method of Chen *et al.*, absent evidence to the contrary, the skilled artisan would understand that the method of Chen *et al.* includes administration to a lymphoid cell according to claim 2. Furthermore, given the oral route of administration, the skilled artisan would also understand that the host cell of Chen *et al.* includes a gut-associated lymphoid cell according to claim 3 in the intestinal lumen according to claim 27.

Chen *et al.* contemplates the method wherein the delivery step is through oral administration according to claim 6 (*Id.*) and 9; wherein the nucleic acid is further protected by a coating according to claim 7 which is an enteric coating according to claim 8 (*i.e.*, PLG; see especially the third paragraph on page 5758); wherein the sequence is a DNA sequence according to claim 10 which is a plasmid according to claim 11; and that the method can be used

to generate an antibody response in a vertebrate host according to claim 25 (see especially Figure 2 and the caption thereto).

The method of Chen *et al.* comprises all of the limitations of the instant claims; therefore, the claims are anticipated by Chen *et al.*

Claims 1, 2, 4, 10-12 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Fu *et al. Mol Med.* 1997 Jun;3(6):362-71 (made of record in the IDS filed 18 January 2003).

Fu *et al.* teaches a genetic immunization method for inducing an antigen-specific immune response, comprising administering to a mammalian host cell a nucleic acid sequence encoding an antigenic peptide operatively linked to one or more control sequences such that the nucleic acid sequence is expressed in a host cell (see especially the first full paragraph in the right column on page 363, the first full paragraph in the right column on page 364, the paragraph bridging pages 365-366 and Figure 3 and the caption thereto). Thus, Fu *et al.* teaches a method comprising all of the limitations of independent claim 1, and dependent claim 12.

Given that lymphoid cells are found throughout the body and at the site of administration in the method of Fu *et al.*, absent evidence to the contrary, the skilled artisan would understand that the method of Fu *et al.* includes administration to a lymphoid cell according to claim 2.

Furthermore, Fu *et al.* teaches immunization of mice by intranasal infection with an influenza virus (see especially the paragraph bridging pages 365-366). As an influenza virus meets the limitations of a nucleic acid sequence encoding a peptide containing at least one antigenic determinant operatively linked to a control sequence, the method of intranasal

administration of virus also meets the limitations of claim 1 and therefore delivery to a nasal lymphoid cell according to claim 4.

Fu *et al.* further contemplates the method wherein the sequence is a DNA sequence according to claim 10 which is a plasmid according to claim 11 and demonstrates that the method can be used to generate a cellular immune response in a vertebrate host according to claim 26.

The method of Fu *et al.* comprises all of the limitations of the instant claims; therefore, the claims are anticipated by Fu *et al.*

Claims 1, 2, 7, 10-12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gregoriadis *et al. FEBS Lett.* 1997 Feb 3;402(2-3):107-10 (made of record in the IDS filed 18 January 2003).

Gregoriadis *et al.* teaches a genetic immunization method for inducing an antigen-specific immune response, comprising administering to a mammalian host cell a nucleic acid sequence encoding an antigenic peptide operatively linked to one or more control sequences such that the nucleic acid sequence is expressed in a host cell (see especially the first and third full paragraphs in the right column on page 107 and Figures 1-4 and the captions thereto). Thus, Gregoriadis *et al.* teaches a method comprising all of the limitations of independent claim 1, and dependent claim 12.

Given that lymphoid cells are found throughout the body and at the site of administration in the method of Gregoriadis *et al.*, absent evidence to the contrary, the skilled artisan would

understand that the method of Gregoriadis *et al.* includes administration to a lymphoid cell according to claim 2.

Gregoriadis *et al.* further contemplates the method wherein the nucleic acid is further protected by a coating according to claim 7 (*i.e.*, liposome; see especially the second full paragraph in the right column on page 107); wherein the sequence is a DNA sequence according to claim 10 which is a plasmid according to claim 11; and teaches that the method can be used to generate an antibody response in a vertebrate host according to claim 25.

The method of Gregoriadis *et al.* comprises all of the limitations of the instant claims; therefore, the claims are anticipated by Gregoriadis *et al.*

Claims 1, 2, 4, 7, 10-12, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishii *et al. AIDS Res Hum Retroviruses*. 1997 Nov 1;13(16):1421-8 (made of record in the IDS filed 18 January 2003).

Ishii *et al.* teaches a genetic immunization method for inducing an antigen-specific immune response, comprising administering to a mammalian host cell a nucleic acid sequence encoding an antigenic peptide operatively linked to one or more control sequences such that the nucleic acid sequence is expressed in a host cell (see especially the third full paragraph and paragraph bridging the left and right columns on page 1422 and Figures 1-3 and the captions thereto). Thus, Ishii *et al.* teaches a method comprising all of the limitations of independent claim 1, and dependent claim 12.

Given that lymphoid cells are found throughout the body and at the site of administration in the method of Ishii *et al.*, absent evidence to the contrary, the skilled artisan would understand

that the method of Ishii *et al.* includes administration to a lymphoid cell according to claim 2. Furthermore, given the intranasal route of administration (see especially Figure 4), the skilled artisan would also understand that the host cell of Ishii *et al.* includes a nasal lymphoid cell according to claim 4.

Ishii *et al.* further contemplates the method wherein the nucleic acid is further protected by a coating according to claim 7 (*i.e.*, liposome); wherein the sequence is a DNA sequence according to claim 10 which is a plasmid according to claim 11; and that the method can be used to generate an antibody response in a vertebrate host according to claim 25 (Figures 1, 2 and 4) or a cellular immune response in a vertebrate host according to claim 26 (Figure 3).

The method of Ishii *et al.* comprises all of the limitations of the instant claims; therefore, the claims are anticipated by Ishii *et al.*

Claims 1-3, 6-12, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Roy *et al. Nat Med.* 1999 Apr;5(4):387-91 (made of record in the IDS filed 18 January 2003).

Roy *et al.* teaches a genetic immunization method for inducing an antigen-specific immune response, comprising administering to a mammalian host cell a nucleic acid sequence encoding an antigenic peptide operatively linked to one or more control sequences such that the nucleic acid sequence is expressed in a host cell (see especially the paragraph bridging pages 390-391, the paragraph bridging the left and right columns on page 388 and Figure 3 and the caption thereto). Thus, Roy *et al.* teaches a method comprising all of the limitations of independent claim 1, and dependent claim 12.

Given that lymphoid cells are found throughout the body and at the site of administration in the method of Roy *et al.*, absent evidence to the contrary, the skilled artisan would understand that the method of Roy *et al.* includes administration to a lymphoid cell according to claim 2. Furthermore, given the oral route of administration, the skilled artisan would also understand that the host cell of Roy *et al.* includes a gut-associated lymphoid cell according to claim 3 including a gut-associated lymphoid cell in the intestinal lumen according to claim 27.

Roy *et al.* further contemplates the method wherein the delivery step is through oral administration according to claims 6 and 9; wherein the nucleic acid is further protected by a coating according to claim 7, which is an enteric coating according to claim 8 (*i.e.*, chitosan).

Roy *et al.* further contemplates the method the sequence is a DNA sequence according to claim 10 which is a plasmid according to claim 11 and that the method can be used to generate an antibody response in a vertebrate host according to claim 25 (see especially Figure 3 and the caption thereto).

The method of Roy *et al.* comprises all of the limitations of the instant claims; therefore, the claims are anticipated by Roy *et al.*

Claims 1-12, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Guy *et al.* (1996) WO 96/31235 as evidenced by U.S. Patent No. 6,126,938 (a continuation of the US National stage application; relied upon for English translation).

Guy *et al.* teaches a genetic immunization method for inducing an antigen-specific immune response, comprising administering to a mammalian host cell a nucleic acid sequence encoding an antigenic peptide operatively linked to one or more control sequences such that the

nucleic acid sequence is expressed in a host cell (see especially the '938 patent at column 2 and columns 4-6). Thus, Guy *et al.* teaches a method comprising all of the limitations of independent claim 1, and dependent claim 12.

Given that lymphoid cells are found throughout the body and at the site of administration in the method of Guy *et al.*, absent evidence to the contrary, the skilled artisan would understand that the method of Guy *et al.* includes administration to a lymphoid cell according to claim 2. Furthermore, given the oral route of administration (third full paragraph in column 5 and column 17), the skilled artisan would also understand that the host cell of Guy *et al.* includes a gut-associated lymphoid cell according to claim 3 in the intestinal lumen according to claim 27.

Given the intranasal route of administration (see especially the second full paragraph in column 5 and column 17), the skilled artisan would also understand that the host cell of Guy *et al.* includes a nasal lymphoid cell according to claim 4.

Guy *et al.* further contemplates the method comprising intravascular administration according to claim 5 (see especially the first full paragraph in column 5); wherein the delivery step is through oral administration according to claim 6 (*Id.*) and claim 9; wherein the nucleic acid is further protected by a coating according to claim 7, which is an enteric coating according to claim 8 (see especially the first full paragraph in column 6); wherein the sequence is a DNA sequence according to claim 10 which is a plasmid according to claim 11 (see especially Example 4); and that the method can be used to generate an antibody response in a vertebrate host according to claim 25 (see especially Example 4 and Figure 9 and the caption thereto).

The method of Guy *et al.* comprises all of the limitations of the instant claims; therefore, the claims are anticipated by Guy *et al.*

Claims 1-4, 6-12, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Compans, R.W. (1998) WO 98/48626.

Compans teaches a genetic immunization method for inducing an antigen-specific immune response, comprising administering to a mammalian host cell a nucleic acid sequence encoding an antigenic peptide operatively linked to one or more control sequences such that the nucleic acid sequence is expressed in a host cell (see especially the first full paragraph on page 2, the third full paragraph on page 11, the paragraph bridging pages 21-22, Example 3, Example 12 and Table 2). Thus, Compans teaches a method comprising all of the limitations of independent claim 1, and dependent claim 12.

Given that lymphoid cells are found throughout the body and at the site of administration in the method of Compans, absent evidence to the contrary, the skilled artisan would understand that the method of Compans includes administration to a lymphoid cell according to claim 2.

Furthermore, given the oral route of administration (see especially the first full paragraph on page 30), the skilled artisan would also understand that the host cell of Compans includes a gut-associated lymphoid cell according to claim 3, which is in the intestinal lumen according to claim 27.

Given the intranasal route of administration (see especially the first full paragraph on page 30), the skilled artisan would also understand that the host cell of Compans includes a nasal lymphoid cell according to claim 4.

Compans further contemplates the method wherein the delivery step is through oral administration according to claims 6 (*Id*) and 9; wherein the nucleic acid is further protected by a

coating according to claim 7 that is an enteric coating according to claim 8 see especially the paragraphs bridging pages 10-11 and 22-23); wherein the sequence is a DNA sequence according to claim 10 which is a plasmid according to claim 11; and that the method can be used to generate an antibody response in a vertebrate host according to claim 25 (see especially Table 2).

The method of Compans comprises all of the limitations of the instant claims; therefore, the claims are anticipated by Compans

Claims 1-3, 5, 7, 10-12, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Content *et al.* (1998) US Patent No. 5,736,524.

Content *et al.* teaches a genetic immunization method for inducing an antigen-specific immune response, comprising administering to a mammalian host cell a nucleic acid sequence encoding an antigenic peptide operatively linked to one or more control sequences such that the nucleic acid sequence is expressed in a host cell (see especially the paragraph bridging columns 4-5, Examples 6 and 7 and Figures 9-16 and the captions thereto). Thus, Content *et al.* teaches a method comprising all of the limitations of independent claim 1, and dependent claim 12.

Given that lymphoid cells are found throughout the body and at the site of administration in the method of Content *et al.*, absent evidence to the contrary, the skilled artisan would understand that the method of Content *et al.* includes administration to a lymphoid cell according to claim 2. Furthermore, given the intraperitoneal route of administration (see especially Example 6), the skilled artisan would also understand that the host cell of Content *et al.* includes a gut-associated lymphoid cell according to claim 3.

Content *et al.* further contemplates the method comprising intravascular administration according to claim 5 (see especially the first full paragraph in column 9); wherein the nucleic acid is further protected by a coating according to claim 7 (see especially the second full paragraph in column 9); wherein sequence is a DNA sequence according to claim 10 which is a plasmid according to claim 11 (see especially Example 1); and that the method can be used to generate an antibody response in a vertebrate host according to claim 25 (see especially Example 6) or a cellular immune response in a vertebrate host according to claim 26 (see especially Example 7).

The method of Content *et al.* comprises all of the limitations of the instant claims; therefore, the claims are anticipated by Content *et al.*

Claims 1-3, 5, 7, 10-12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Donnelly *et al.* (1996) WO 96/00583.

Donnelly *et al.* teaches a genetic immunization method for inducing an antigen-specific immune response, comprising administering to a mammalian host cell a nucleic acid sequence encoding an antigenic peptide operatively linked to one or more control sequences such that the nucleic acid sequence is expressed in a host cell (see especially Examples 4 and 7). Thus, Donnelly *et al.* teaches a method comprising all of the limitations of independent claim 1, and dependent claim 12.

Given that lymphoid cells are found throughout the body and at the site of administration in the method of Donnelly *et al.*, absent evidence to the contrary, the skilled artisan would

understand that the method of Donnelly *et al.* includes administration to a lymphoid cell according to claim 2.

Donnelly *et al.* further contemplates the method comprising intravascular administration according to claim 5 (see especially the fourth full paragraph on page 10); wherein the nucleic acid is further protected by a coating according to claim 7 (see especially the paragraph bridging pages 10-11; wherein the sequence is a DNA sequence according to claim 10 which is a plasmid according to claim 11 (see especially Examples 1-3); and that the method can be used to generate an antibody response in a vertebrate host according to claim 25 (see especially Figures 1-2 and the captions thereto).

The method of Donnelly *et al.* comprises all of the limitations of the instant claims; therefore, the claims are anticipated by Donnelly *et al.*

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER